

**REMARKS/ARGUMENTS**

Applicants have carefully studied the Final Office Action mailed on September 17, 2004 and gratefully acknowledge the Examiner's consideration of the §1.131 Declaration and withdrawal of the written description rejection. The Applicants now present the following arguments and remarks, which are intended to respond fully to all points of rejection raised by the Examiner and accordingly, to place the claims in condition for allowance.

**Status of Claims**

Claims 1-7, 12-27, 33-35, and 39-58 are presently pending.

Claims 8-11, 28-32, and 36-38 have been cancelled without prejudice as drawn to a non-elected invention. Applicants reserve the right to prosecute the subject matter of these claims in a related continuing application.

Claims 12-27, drawn to a process and a kit, have been withdrawn from consideration, but they should be rejoined upon an indication of allowable subject matter related to the pending product claims.

Claims 40-58 have been added in the amendment.

Claims 2-5, 12-14, 16, 18, 20-25, 27, and 33-34 have been amended.

No new matter has been added.

Claims 1-7, 33-35, and 39 stand rejected.

**Election/Restriction**

The Applicants acknowledge that non-elected claims 12-27 will not be rejoined with the elected product claims until a product claim has been allowed. As discussed below, Applicants have amended the product claims to place them in proper condition for allowance. Accordingly, Applicants now request a rejoinder of claims 12-27.

**Rejections under 35 U.S.C. § 112: Second Paragraph**

The Examiner has rejected claims 2-5 and 33-35 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has raised four grounds for this rejection, which are addressed in turn (the parenthetical designations refer to the corresponding paragraphs in the Office Action):

(5.1) The Examiner has stated that claim 2 is vague and indefinite because there is no antecedent basis for “the gene” and because the limitation “mutation” does not have a point of reference. In response, the Applicants have added the limiting phrase “wherein the nucleic acid is a gene.” This amendment provides an antecedent basis for “the gene” and a specific point of reference for the term “mutation.”

(5.2) The Examiner has rejected claim 3 as vague and indefinite because there is no antecedent basis for “the gene.” In response, Applicants have amended claim 3 to depend from claim 2, thereby incorporating the antecedent phrase “wherein the nucleic acid is a gene.”

(5.3) The Examiner has stated that claim 4 is vague and indefinite because there is no antecedent basis for “the defect in expression”. In response, the Applicants have (i) removed the phrase “the defect in expression”; (ii) replaced it with the phrase “the mutation”; and (iii) amended claim 4 to depend from claim 2, thereby incorporating the antecedent phrase “wherein the nucleic acid is a gene comprising a mutation”.

(5.4) Finally, the Examiner has stated that claims 4-5 and 33-35 are vague and indefinite because the metes and bounds for the limitation “MCOLN1” are undeterminable for the reasons

of record stated in section 7.2 of the previous office action. In response, the Applicants respectfully reassert their previous contention that since all claims relate to structure (SEQ ID NOS:1-3) as well as to function (characteristics of MCOLN1), there is no ambiguity to the skilled artisan. Nevertheless, to expedite prosecution of these claims, the Applicants have removed the term "MCOLN1" from the claims. In addition, the Applicants have replaced the phrase "a gene encoding functional human MCOLN1" in claim 33-34 with the phrase "the isolated nucleic acid of claim 5."

On the basis of these changes and remarks, Applicants respectfully submit that the grounds for rejection under this provision have been overcome, and that accordingly, the rejection should be withdrawn.

**Rejection under 35 U.S.C. § 102(e)**

The Examiner has sustained the rejection of claims 1, 5-7, and 33-35 and has rejected new claim 39 as anticipated by the Curtis et al. and Lal et al. patent publications. These publications have effective filing dates of April 7, 2000 and August 17, 1999, respectively. According to the Examiner, these publications anticipate claims to nucleic acids encoding MCOLN1, corresponding amino acid sequences, and expression vectors comprising the nucleic acid.

In response, the Applicants submit here a modified version of the previous Declaration Under 37 C.F.R. §1.131. Applicants gratefully acknowledge the Examiner's consideration of this Declaration in the previous response. In this action, the Examiner has pointed out that this Declaration is deficient for two reasons: (i) it does not contain the signatures of all inventors; and (ii) it does not indicate where the inventive acts took place.

The modified Declaration cures these two deficiencies. First, it is executed by all inventors of the claimed subject matter, in conformance with M.P.E.P. §715.04(1)(A). Second, it includes the statement that the activities described therein were completed in the United States, in conformance with 37 C.F.R. 1.131. Thus, the Declaration establishes the inventors' reduction to practice prior to August 17, 1999 of the subject matter of claims 1, 5-7, 33-35, and 39. While respectfully disagreeing with the Examiner's grounds for rejecting claim 35, the Applicants note that the issue has been mooted by the Declaration, which establishes prior invention of the nucleic acid component.

In light of the accompanying Rule 1.131 Declaration and the foregoing remarks, the Applicants respectfully request withdrawal of the rejection under this provision.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants believe that each of the presently pending claims in this application is in condition for allowance. Accordingly, Applicants respectfully request that the Examiner enter the foregoing amendments and remarks in the file history, and pass this application to issue. If the Examiner believes that a telephone conversation

would help advance the prosecution in this case, the Examiner is respectfully requested to call the undersigned attorney at (212) 527-7665.

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Respectfully submitted,

By 

Paul F. Fehlner, Ph.D.

Registration No.: 35,135

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorney For Applicant